# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of adjustment of environmental factors on sleep quality of patients admitted to the cardiology unit of Shahid Modarres Hospital of Saveh

## Protocol summary

**Study aim**
Determining the effect of adjustment of environmental factors on sleep quality in patients hospitalized in Coronary Care Unit

**Design**
Randomized clinical trial with control group, parallel groups, one-blinded.

**Settings and conduct**
The present study will be conducted at Modarres Hospital on patients hospitalized in Coronary Care Unit. The analyzer will not know how to place the samples in the intervention and control group.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: The willingness to participate in the study Passes at least 6 days after hospitalization Don't use of somnifacient drugs 18 to 65 years old Exlusion criteria: Unwilling to participate in the study History of sleep disorder

**Intervention groups**
For intervention group, measures are taken to moderate environmental factors, including downsizing of telephone calls, alarms of devices, shutdown of all additional lights during the night, and use of low light during the daytime. Control group samples are in normal condition and receive standard care.

**Main outcome variables**
Sleep quality

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20161210031328N8**
Registration date: **2018-07-08, 1397/04/17**
Registration timing: **registered_while_recruiting**
Last update: **2018-07-08, 1397/04/17**
Update count: **0**

**Registration date**
2018-07-08, 1397/04/17

**Registrant information**

**Name**
Mahbobeh Sajadi

**Name of organization / entity**
Arak University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
1639-01-14, 1017/10/24

**Expected recruitment end date**
2639-05-24, 2018/03/03

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of adjustment of environmental factors on sleep quality of patients admitted to the cardiology unit of Shahid Modarres Hospital of Saveh

**Public title**
Adjustment of environmental factors on the quality of sleep in patients admitted to the Cardiac Care Unit

**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
The willingness to collaborate in the study Admission for at least 6 days Do not use hypnotic drugs Having a range of 17 to 64 years old Not having a specific disease, such as hepatitis
**Exclusion criteria:**
Surrender patient sleep disorder Transferring the patient to other parts
**Age**
From **17 years** old to **64 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **70**
**Randomization (investigator's opinion)**
Not randomized
**Randomization description**
groups over successive but equal intervals.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
The analyzer will not know how to place the samples in the intervention and control group.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Samples were randomly assigned to two intervention and control groups using randomized block assignment.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
کمیته اخلاق دانشکده علوم پزشکی ساوه
**Street address**
Saveh University of Medical Sciences, Madar Sq., Shariati St.
**City**
Saveh
**Province**
Markazi
**Postal code**
3919676651
**Approval date**
2638-10-17, 2017/07/25
**Ethics committee reference number**
IR.SVEHUMS.REC1396.13

## Health conditions studied

### 1

**Description of health condition studied**
Sleep quality
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Sleep quality
**Timepoint**
Before the study and six days after the first day of hospitalization
**Method of measurement**
Pittsburgh Sleep Quality Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: from the third day after the hospitalization, adjustments to the environmental factors (including reduction of light and surplus voices) are performed consecutively for three days.
**Category**
Lifestyle

### 2

**Description**
Control group: from the third day after hospitalization without any changes in the physical conditions of the unit and without any additional work until the 6 days will be monitored.
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Modares Hospital
**Full name of responsible person**
Elham Farhadi
**Street address**
Shahid Modares Hospital, Modarres Sq.
**City**

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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Saveh University of Medical Sciences
**Full name of responsible person**
Hamid Reza Baradaran
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Saveh University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Saveh University of Medical Sciences
**Full name of responsible person**
Neda Fayazi
**Position**
Master of Nursing
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable of people.
**When the data will become available and for how long**
The beginning of the access period is 12 months after the results are published.
**To whom data/document is available**
For all researchers
**Under which criteria data/document could be used**
In order to utilize scientific purposes and mention the source used.
**From where data/document is obtainable**
nedafayazi10@yahoo.com Neda Fayazi
**What processes are involved for a request to access data/document**
After receiving the email from the requester, the information will be sent within 2 to 3 business days.
**Comments**